IN THE DISTRICT COURT OF THE UNITED STATES IN AND FOR THE SOUTHERN DISTRICT OF FLORIDA

MARY GREEN, a widow,

Plaintiff,

vs.

AMERICAN TOBACCO COMPANY, a corporation,

Defendant.

No. 8505-M-Civ-EC

EDWIN M. GREEN, JR., as Administrator of the Estate of EDWIN M. GREEN, Deceased,

Plaintiff,

vs.

AMERICAN TOBACCO COMPANY, a corporation,

Defendant.

No. 8070-M-Civ-EC

Property of: Ness, Motley
Main PI File Room
Charleston, SC

Federal Courthouse,
Miami, Florida,
November 25, 1964,
9:30 o'clock a.m.

The above-styled cases came on for further hearing before the Honorable Emett C. Choate, United States District Judge, pursuant to adjournment.

APPEARANCES:

As heretofore noted.



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Bring the jury in.

(Thereupon, the jury returned to the courtroom after which the following proceedings were had:)

THE COURT: If you are ready, you may proceed.

Thereupon:

DR. BERNARD G. GREENBERG

was called as a witness on behalf of the Defendant, and being first duly sworn, was examined and testified on his oath as follows:

THE COURT: State your name, address and occupation.

THE WITNESS: My name is Bernard G. Greenberg. I live in [DELETED] I am a bio-statistician, a Professor of Bio-statistics.

THE COURT: Where?

THE WITNESS: At the University of North Carolina.

THE COURT: Give us briefly your background in education and qualifications in your particular field.

THE WITNESS: My undergraduate training was at the City College of New York in New York City, where I was a major in Mathematics and received a Bachelor of Science degree.



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I have worked in the New York State Department of Health and the Bureau of Census in the past.

After the war, I was a student and a staff member at North Carolina State College where I received a Doctor of Philosophy degree in Experimental Statistics.

Since 1949 I have been a Professor of Bio-statistics at the University.

THE COURT: Proceed.

DIRECT EXAMINATION

BY MR. BRADFORD:

Q Doctor, tell us what bio-statistics is?

A Well, statistics is the science involving the design of studies, the collection of data, the processing of the data and the analysis thereof. This is statistics in general.

Bio-statistics would be applying these principles and practices to the field of biology or life. Bio comes from the Greek meaning life. So, we are applying statistical methods to life and life problems.

Q How long have you been at Chapel Hill and the University of North Carolina as a professor?

A Since 1949.

Q What type of student do you teach?

A Well, I am in the School o f Public Health,



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which is a graduate school.

We train doctors, nurses, engineers, statisticians, bio-statisticians in our regular School of Public Health. I also teach medical students in the medical school, dental students in the dental school and nurses in the school of nursing.

Q Do you teach any graduate students, that is, doctors or people who have graduated and who want to learn how to apply statistics to their work? Do you have a course beyond the normal course, beyond the regular education in their field?

A All of our students are graduate students. About a third of them, perhaps, are physicians.

Q Tell us something about your organizations that you be' ,ng to.

A Well, the department I am Chairman of consists of about eight persons at the professorial level or above. These are all persons with a Ph.D. degree in this field.

We have about five or six persons who are semi-professional with Bachelor's and Master's degrees, and then we have a clerical and secretarial staff of about twenty to twenty-five persons.

Q Do you have a nything to do with the gathering or reviewing or before publication of Public Health records or



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United States vital statistics?

A Not of official records themselves, no.

Q Do you have anything to do with the Public Health records as such?

A Well, medical studies and dental studies, nursing studies, Public Health studies that are conducted at the University of North Carolina, of course, I am a consultant, I and persons in my department, are consultants to these individuals that are interested in doing medical studies. We provide the statistical advice and consultation to help them in these.

Q Do you devise means or ways by which they set up their mechanism to go about these studies to arrive at a conclusion?

A This is our primary function--to help them to design a study to answer the questions they are trying to answer.

Q What about your own research? Do you do research yourself in this field?

A Well, most of the research that I call my own research is in statistical methods. It is more or less mathematical, to devise new and better methods to help persons who are doing research have these methods available for them. This I would call my own research.



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The other research I collaborate with other persons on their problems.

Q Would you tell us, sir, what professional organizations you belong to that have to do with your particular field of study?

A You mean of which I am a member?

Q Yes.

A The American Statistical Association, the American Public Health Association, the Biometric Society, the Institute of Mathematical Statistics, Royal Statistical Society, Population Association of America and perhaps some other smaller in nature.

Q What about publications? Do you publish for public consumption or for those in your field articles or books, or anything of that nature?

A I have published perhaps sixty or seventy articles and some books, yes.

Q Give us a brief rundown on the scientific journals or books where these publications appear, please.

A I have a list of these. May I use this as a reference?

Q Yes.

A I do not profess to remember all of these. I will give an example of some of them:

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The Journal of the American Statistical Association;

The Journal of Bacteriology;

The American Journal of Syphilis;

Human Biology;

Biometrics, which is a statistical journal in Biology;

American Journal of Public Health;

Canadian Journal of Public Health;

Internal Medicine;

American Journal of Tropical Medicine and Hygiene;

American Statistician;

Annals of Mathematical Statistics;

American Journal of Obstetrics and Gynecology;

Proceedings on the Second Conference on the Design of Experiments in Army Research Development and Testing;

Proceedings in the Statistical Techniques in Missile Evaluation Symposium;

American Journal of Medicine;

Journal of the Royal Statistical Society;

Annals of Surgery; and then I have several books in which I have written chapters.



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Then I am co-author of a book on Statistical Methods.

I have also written articles for one of the Encydopedias on Statistical Methods.

Q In your work you mention you have to relate your work to Public Health.

Do you relate any of your work to chronic diseases, such as cancer studies and things of that nature?

A We have several research projects in our dpeartment involving cancer themselves in which we provide service to a group of medical schools throughout the South-eastern part of the United States.

In terms of chronic diseases, in answering that question. I am associate editor of the Journal of Chronic Diseases.

THE COURT: Cancer is not a chronic disease, is it?

THE WITNESS: It would be classified as a chronic disease.

BY MR. BRADFORD:

Q Have you held any official position in any of the organizations that have to do with vital statistics or your field or specialty?

A In the organization that I mentioned, I have



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been Chairman of the Statistical Section of the American Public Health Association.

I have been Chairman of the training section in the American Statistical Association.

I am presently Chairman of the 1964 program for the American Statistical Association Annual Meeting.

I have been a consultant to many organizations in the Public Health Service and other agencies.

Q Doctor, on a statistical basis, does the fact that there are two things that may be increasing numerically when you count them at the same time prove that one is causing the other or related to the other thing?

A No. This is what we would call a time series. Simply because two kinds of events are related in time does not mean that they are necessarily--that one is necessarily causing the other.

For example, let us take the number of television sets that are in use in the United States. If we count this number in 1946, 1947, 1948 as one series and alongside of it we put the number of persons who are mentally defective or that have mental disease, we probably would find a very close relationship between the two.

The fact we have an increase in the number of television sets and an increase in the number of mentally



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defectives, this does not mean persons who are mentally defective get it from watching TV.

Q It is a crude example, but is that what you mean?

A As a matter of fact, there is a classical example which is quoted in scientific communities to illustrate this.

Q I read one about Scotch and soda.

A May I use the blackboard?

THE COURT: For what purpose?

THE WITNESS: I would like to illustrate the classic example of the mistake persons make when they see two events related in time and why this---

THE COURT: Well, we know that unrelated events, such as, say, war and the plowing of corn fields does not mean anything. Let us get back to medicine. Stay in the medical line. We are not interested in television sets.

If people with lesser minds buy more television sets, I don't know. That is not really what we are trying to inquire about in this case.

BY MR. BRADFORD:

Q Doctor, do you teach bio-statistics to epidemiologists among the people that you teach?

A Yes. I teach several courses.



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The first course which all students in the School of Public Health are required to take is General Statistical Methods. Those persons who are interested in studying epidemiology as a discipline, I teach a special course called Statistical Methods for Epidemiologists. In fact, I have taught this at four or five of the universities as a visiting professor.



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Q. Do you have anything to do with any standing committees in the National Office of Vital Statistics? Do you have any connection with that?

A. Yes. I am a Member of the standing committee, which is an advisory committee to the National Vital Statistics Division, which is the agency in the Federal Government which is responsible for the collection of vital statistics in this country.

Q. Doctor, can a common factor, an hypothesis as to cause, be misleading in the interpretation of statistical data such as retrospective studies of a given disease or germ?

MR. HASTINGS: Your Honor, I think this is in the realm of possibility and we object because anything is possible.

THE COURT: I will say again that we know a common factor is not always a basic factor in drawing many conclusions that are beyond the expert theory. If you want to ask him about the accepted methods of approach, that would be within his field. Otherwise, one guess would be as good as another.

BY MR. BRADFORD:

Q. Doctor, what would be an accepted method of approach in studying statistics and particularly in disease



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and its relation with some cause or some suspected cause?

A. I would have to use the blackboard on this, sir. (Demonstrating on blackboard) In order to prove causation in a disease process, generally speaking what we must first start out with, I'll just use as a diagram, a group of persons in whom we are interested, and we call this a target group population. And the words "target group population" is a very meaningful one because it is the group we are aiming at. We are shooting at this as a target. It may be all mankind, it may be all males, it may be all persons in the United States.

It is important, when we start this particular kind of study, that we define not only the persons involved but also the disease that we are talking about.

There are many examples in the statistical literature and in the medical literature where persons have failed to take proper precautions in defining who it is that they are talking about, what the person is and what kind of disease they have been led to the erroneous conclusion. One of the most common of these, for example, is the mistake that was made right after the war in the case of antihistamines where a person was interested in trying to develop a drug which would cure the common cold and in so



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doing he failed to define what he meant by the common cold. And as a result, he ended up by thinking he had a cure for the common cold; but he instead, as it turned out later by the council of drugs of the American Medical Association, he was treating a condition known as chronic allergic rhinitis, which I will write on the board and explain it.

MR. HASTINGS: I don't believe this witness is qualified as a medical doctor and should not be getting into medical terms. I think it's improper.

We were not permitted to have the chief statistician of the American Cancer Society to speak on medicine, but he was only to speak on statistics.

THE COURT: Let's keep it close to the subject at hand. I will overrule the objection.

THE WITNESS: (Continuing)

Rhinitis means a running nose and eyes as the result of an allergic condition, which today we know can be cured by antihistamines. It does not have any effect at all on the cold itself.

And this was a mistake which this investigator made because he failed to define the disease in mind. And we have done this. After we have defined the kind of persons we are aiming at, we have got to draw some kind of sample.



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Obviously we cannot study all persons in the world. We cannot study all the males, we cannot study all the persons in the United States. We must draw a sample of persons, a sample of subjects on whom we intend to do the study.

At this point, this sample has to be chosen according to a scientific method, what we call the random sample and representative so that whatever you are going to conclude about this would also apply to the target that you are aiming at.

At this point here, if we want to study diseases or the ways of preventing disease, we divide this group.

Let's say we are considering the simple effect of a drug or we want to find out if something is the cause of a particular disease. At this point the investigator who is conducting the study must divide his sampling subject into two groups. That is a sort of north track and a south track.

At this point here, by tossing a coin or drawing cards from a deck, he must decide whether a person is going to get, let's say, the drug or the particular factor that is suspected of causing the disease, and he is going to get some kind of control which we sometimes call a placebo--placebo simply meaning "I shall please."



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This step here is the most crucial step in this process, because this must be under the control of the investigator. We cannot allow people to volunteer if we expect to end up with the causation of disease.

This must be under the control of the investigator and he, himself, must turn to some kind of objective device like tossing a coin so he doesn't tend to put sick patients on one and the well patients on the other, or the poor ones on one and the rich ones on another and so on. He doesn't allow any personal bias to get involved in his assignment.

After assigning the particular factor involved, whether it is a drug to cure a disease or a factor which may cause a disease, it is important that the person who does this not know which of the two drugs or factors is involved. That is, it is important, if you are talking about lung cancer and cigarette smoking for the investigator not to know whether the person is smoking or not smoking.

It is important also, obviously--and this would be impossible in such a study--for the person not to know whether he is getting the drug or a control.

After the drug or the factor has been administered--and it may take years to administer this factor--



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we have a waiting time, and we have to choose the waiting time so that it is optimal in terms of measuring the response we want.

Obviously, if you make your final observations too soon--if you do them too soon, you are going to miss the effect of the drug or you are going to miss the effect of the factor.

For example, if you are interested in cigarette smoking as a possible cause of lung cancer, if you ended the study after one day or one week or one month, obviously you are doing this too soon.

So we have to wait a optimal period of time. After that period of time you may have to do side experiments to determine this waiting time. You make your determination to find out how many have developed the particular response you are talking about--the percentage here and the percentage here.

Now, this particular design then tells us if there is a difference between these two groups; and if there is a difference, we can say then it was this particular factor involved. And, of course, it applies to this sample that we are talking about.

You will notice in this that I have shown an arrow proceeding in this direction. This means that we are



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talking about an experiment or study which goes forward in time. The name given for this is prospective study or anterospective and so on. This is the usual way that we do it.

There is one other other problem that we have to concern ourselves with, although there may be differences here. We have to find out if the difference also would apply back here to the target group we are aiming at.

In order to do that, statisticians have a rather rigorous procedure known as a test of significance or a test of statistical significance which allows them to generalize facts. It tells them the probability of making a mistake should they generalize that to the target population.

As I have pointed out, in all of this, this is forward going in time. Many of the studies that have been done in this area have been what we call retrospective or, if you want another word, it would be ex post facto, after the act has happened. You look back over your shoulder, so to speak, to try to find out why it has happened.

For example, in the case of lung cancer, what many persons do, they will take a group of persons who have



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lung cancer; that is, not a random sample of persons who have lung cancer, but persons who come to a medical clinic or who have been referred to a clinic which is known because of its outstanding reputation for treating of lung cancer--and they will try to get a group of other persons, again not random in terms of population, who do not have lung cancer.

What the investigator usually does is to go back in time and find out what proportion in this group have done some event or other, such as smoking, have worked in a mine, have worked in the nickel industry, have worked in the chromate industry, how many have been urban or rural, et cetera.

They look at a certain percentage who have done some event or some who have experienced some event. And similarly they look back in time in this group. Those persons who do not have lung cancer, to see what proportion of them have that same characteristic, such as smoking. And if this group here happens to have a larger percentage of this particular characteristic, the assumption made by some investigator of this kind is that this is causing that.

Obviously this is not the case, because if you want to prove causation, you must follow this design. This is the design.



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For example, this is the one that is prescribed by the Food & Drug Administration in order to get a drug accepted on the market in order to prove its effectiveness. It must go through this process.

There are other problems involved such as what we call a double blind. That is, the person doesn't know what drug he is getting, the investigator doesn't know what drug he's getting. And there are many examples in the literature.

I don't know if you want to take up the time on that.

Q. Go ahead.

A. Or what happens if you don't follow these rules.

Q. Doctor, is the retrospective studies such as you have outlined up there a good study upon which to base a conclusion as to the cause and effect of anything?

A. Not for causation, absolutely not.

Q. Now, the study that you put up first, as to the prospective study, is that conclusive, or does that establish a scientific fact, or is further work and further scientific relations back to the figures necessary to come to a sound conclusion?



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A. Well, sir, the term prospective is used very loosely, if I might say so.

The term itself, prospective, means simply going forward in time. The design that I illustrated has something quite different from many so-called prospective studies such as have been done in the field of cigarette smoking and lung cancer. That is, the difference between my design and many of the prospective studies which have been done is that at this point here, the investigator must decide who is going to smoke and who is not going to smoke.

And he, himself, doesn't make that decision. He turns to some objective device like tossing a coin.

Now, in the prospective studies that have been done in this area, this was never done. Obviously the person had decided five, ten, 20 or 30 years before that time when they started to smoke whether they would smoke and how much they would continue to smoke throughout their life.

In other words, there is no control involved. The person decided to do what he wanted to do and then proceeds throughout life to do it.



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Q. As a result of that study, does that figure have any relation whatsoever in establishing the cause or effect of anything?

A. No. Such a study is nice in the sense that it at least is prospective in time and it gets away from one of the retrospective aspects. But it is still retrospective in that you are projecting backwards to why did he start to smoke in the beginning and also the fact that he is going to volunteer himself to smoke.

So, you have not overcome the most crucial part of such a design, namely, this point here, which we call the allocation of the patient to treatment. This was not under the control of the investigator.

Q. Doctor, in your study, have you taken into account and from a statistical angle, the apparent increase in cancer cases reported as opposed to the possible not increase? In other words, the fact that there are numbers counted and the number may be greater today than otherwise or were back ten years ago, have you made a study in that field?

A. Yes.

Q. Will you tell us, sir, what factors enter into this computation of the figures that look like there



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may be a rise in the numerical number of cases of lung cancer?

A. Of lung cancer?

Q. Yes.

A. Well, of course, there are many reasons why lung cancer appear to be on the increase. How much of it is real I don't really know. I don't think other persons really know, and let me tell you some of the reasons why I think there are difficulties in interpreting how much real increase there has been.

First of all, I think everybody here knows that there has been an increase in the age distribution of our population. That is, we are getting an older population. I am sure the people in Florida are quite aware of this.

For example, at the beginning of this century, let's say 1900, we had probably less than 10 per cent--I think it's something like 8 per cent or 9 per cent--of the population was under or was over fifty years of age. Today, 60 years later, this figure has almost doubled. I think we have about 18 per cent of our population over fifty years of age.

In terms of percentage, that looks like a doubling. However, in terms of persons, at the turn



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of the century, we had about 7-1/2 million persons over age fifty. Today we have over 30 million. This is an increase of four times in terms of the number of persons who are over age fifty.

Why is it important?

Well, lung cancer, for example, is a disease of older persons. It starts around middle age, and very little of it, although you can have it in children--very little of it is in that early and middle-age period.

So the first thing we have to worry about is the aging of the population. Now, statistically, we have ways for adjusting for this. There is such a thing called an age-adjusted death rate. So we can sort of fudge or adjust for this factor.

But there are other aspects of aging that have to be considered with it. One of them is the fact that persons who sought of graduate to the age of fifty today aren't perhaps as hardy as the person who became fifty half a century ago.

That is because of newer methods of medicine, antibiotics, et cetera, and ways of treating, for example, diseases like tuberculosis, which killed many persons in their twenties.



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We find many persons who are able to reach the age of fifty who years ago would not have been able to do so. So that even though we can adjust for the age distribution, we have not adjusted for who these people are. They are not as healthy as they were 50 or 60 years ago when they reached that point.

Also, we have to consider the kind of environment they are living in and the problems that they have as individuals, and the stress factors that are put on these persons.

For example, as little as 20 or 25 years ago, 60 per cent of our population was in the group twenty to sixty-five. That is, the working group, the group-supporting society, so to speak, providing goods. And there were 40 per cent either young children or under age sixty-five. Today that percentage has moved from 60 per cent down to 50 per cent.

That means, for example, that 20 or 25 years ago three persons were working and supporting three persons at home. Today--let me correct that. Three persons were working and supporting only two at home. Today it has been three and three.

That is, 25 years ago, my father and, in



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a sense, that generation, only had to support two persons. Today in our generation persons between twenty and sixty-five haveto support three persons. There is an increase of 50 per cent of the load on your shoulders, so to speak. Obviously, this has added to our stress factors.

This is one of the factors, I think, that has to be considered in looking at the apparent rise in lung cancer.

Other factors involve the ways that we get the data. The data come from death certificates, and it is important to know how we do these and some of the limitations involved.

In fact, if you study the methods--

MR. HASTINGS: I think the doctor has gone far afield. He is not a medical doctor.

THE COURT: Don't tell us about death certificates unless you have investigated it.

MR. BRADFORD: I can clear that up.

THE COURT: He can only testify as an expert in the things that he is versed in, that he personally investigated.



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Q Doctor, do you have to investigate death certificates in your work and the problem of correlating those things?

A I teach a course to medical students and doctors on how to fill out the death certificates, sir.

Q Do you have to know generally what goes in them for statistical purposes that go to the Bureau of Vital Statistics?

A Yes, sir.

Q Tell us the problems of the death certificates and the number of autopsies that are shown in death certificates.

MR. HASTINGS: Your Honor, again, I feel he is not competent to testify as to this.

THE COURT: Sustained.

MR. BRADFORD: He teaches doctors how to fill them out.

THE COURT: A teacher is not an expert. A teacher is the fellow that gives the information. He may be an expert, and ought to be an expert, but many times he is not.

Now, if he is an expert on death certificates, if he has made a survey of them, an extensive survey, did the things he said ought to be done in any survey, then we



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will let him tell us about.

BY MR. BRADFORD:

Q Doctor, have you made any survey of death certificates in the United States or in any large populated areas that is a sample?

A I have studied death certificates as an employee in the New York State Department of Health.

It was my function to study death certificates, to study how to classify the causes of death in death certificates and how to analyze the deaths from the death certificates.

MR. HASTINGS: I move to strike the answer as not being responsive to the question.

THE COURT: Sustained.

Doctor, what we want to know is have you carried on just exactly what you say is necessary to carry on any investigation?

THE WITNESS: Yes.

THE COURT: Have you gone to the hospitals? Have you gone to the doctors and compared the death certificates and ascertained what errors, what deficiencies have existed over a large number?

THE WITNESS: Yes, we have. We have conducted---

THE COURT: Not "we." You.



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THE WITNESS: I, as a member of a team, sir, have conducted studies where we have---

THE COURT: Tell us what you did, not what you conclude you did. What did you do?

THE WITNESS: We were interested in seeing if doctors filling out death certificates put on the death certificate the same cause of death and disease as was recorded in the hospital record.

We, therefore, compared the death certificate with the hospital record.

We were primarily concerned in that area with cardiovascular disease.

MR. HASTINGS: May I question the doctor, your Honor, in reference to this if he is going to be permitted to testify?

THE COURT: Go ahead.

MR. HASTINGS: Doctor, how many doctors do you personally talk to in reference to this in terms of their death certificates and how many doctors did you interrogate?

THE WITNESS: Doctors who filled out the death certificates?

MR. HASTINGS: Yes.

THE WITNESS: In this particular case, none. We used the records in the hospital.



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MR. HASTINGS: That is all. We move that is incompetent to testify, your Honor.

THE COURT: You can testify what hospital, how many records and over what period of time you conducted these.

THE WITNESS: This was done at the North Carolina Memorial Hospital in Chapel Hill. This was done approximately five years ago when we studied two years of death certificates.

THE COURT: He can testify as to what he found and the difference, but not his conclusions in any way, shape or form.

MR. HASTINGS: He said there was a difference between what the doctor found and what was placed on the death certificate.

THE COURT: Well, the doctor and the nurse is another. The nurse, of course, is under the doctor and she generally fills out the---

MR. HASTINGS: May I inquire on that point?

THE COURT: Yes.

MR. HASTINGS: Who is it that fills out the death certificate? The doctor, is it not?

THE WITNESS: The body of the certificate is filled out by the person, the funeral director or person who requests the burial permit.



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The medical certification of the cause of death must be filled out by a physician or a coroner if a physician was not in attendance.

MR. HASTINGS: The diagnosis of what the cause of death was?

THE WITNESS: Filled out by a physician or coroner.

MR. HASTINGS: And he signs his name to that?

THE WITNESS: Yes.

MR. HASTINGS: So, in terms of looking at what the death certificates or hospital records show and make a survey in terms of something, whether the doctor did or did not find that, did you ever discuss that with the doctor as to what his findings were?

THE WITNESS: No.

MR. HASTINGS: Did you ever publish anything along those lines?

THE WITNESS: In this particular study, no.

As a statistician and in the New York State Department of Health part of my job was to query doctors about--by mail--as to proper terms, improper terms or omissions on the medical certifications as to cause of death.

MR. HASTINGS: Your Honor, again we submit he is talking now about something that he has never questioned



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the doctors.

Was this ever published?

THE WITNESS: No.

MR. HASTINGS: This is some study he has done where he never interrogated one single doctor and never published any paper on it.

THE COURT: I think we are kind of ranging the field now.

MR. HASTINGS: It would be hearsay.

THE COURT: It is a relatively small hospital and a difference in records. I do not think, according to his example of what you have to do to come up with a statistical fact, that is dependable and would be sufficient.

MR. BRADFORD: Your Honor, I think his education and his training and his investigation in the State of New York and what he did there added to what he did in North Carolina would make him qualified.

THE COURT: How many articles did he write?

MR. BRADFORD: I don't know.

THE COURT: He said he has to have a large group selected at random. I agree with him. Otherwise, you come into, perhaps, of what we might call local areas or local differences, and they are not uniform.

I do not think there is any question everybody



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has testified in this case that death certificates are often somewhat erroneous or misleading.

That is very understandable because we all know that death certificates are made out by the doctor and he may not put everything down. He may make a mistake and so forth.

MR. ERADFORD: I understand I am not permitted to pursue that subject further?

THE COURT: Not on the line you are now on.

BY MR. ERADFORD:

Q Doctor, do you know from a national scale as to what percentage of death certificates show autopsies?

MR. HASTINGS: Are we speaking about something he read? If he is going to quote somebody else, this is something we were not permitted to go into.

MR. BRADFORD: He can obtain this from vital statistics.

THE WITNESS: I would have to quote a figure that is put out by the Federal Agency, something I have not done myself.

THE COURT: I do not think anybody objects to that. We know that the scale of autopsies are up and down.

BY MR. BRADFORD:

Q What is the figure of the Government Agency?



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A Well, less than 10 per cent of the experts in the nation have autopsy data on them.

THE COURT: That would be true no matter what happens under our present laws; is that right?

THE WITNESS: Well, the trend, of course, is increasing because we have a medical-legal system now wherein many cases the coroner is required by law to get qualified help, and this has increased the number. There is no way for the coroner or anybody else to perform an autopsy on anybody. He has to get family permission, yes.

BY MR. BRADFORD:

Q Sir, when did the Bureau of Vital Statistics first contain information as to the types of lung cancer as to whether they were primary or whether they were just a respiratory tract infection or things of that nature?

A Well, in 1939 with the fifth revision of the International Statistical Classifications of the causes of death they had a category or rubric, as it is called, devoted to cancer of the bronchus and lung.

Q Did they, in that first move, require specification as to primary and secondary?

A No, they did not. They were all lumped together.

Q Did they require any identification of the



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types of cancer?

A No, they did not.

Q Was that procedure changed later on and, if so, tell us what amendments or changes were made in the requirements?

A The International Statistical Classification is revised roughly every ten years.

The next revision came under the World Health Organization, and that was put into effect in 1949.

At that time they did specify whether the lung cancer was primary or whether it was unknown as to whether it was primary or secondary. However, they lost some of the advantage they previously had in the fifth revision when they separated out the bronchus in the lung from the trachea.

When they made this change, starting in 1949, although they separated out whether it was primary or not, they threw back into the part cancers of the trachea so that you have this whole group.

It was not really until 1958 that we now have the exact data as to what is really a primary cancer of the bronchus and lung and nothing else.

Q Do these statistics today tell you what type of cancer it is?

A No, they do not.



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Q Doctor, from your statistical study, could you tell us whether or not in the last twenty years there has been a steady increase in the number of lung cancer cases or is the rate of increase dwindling or is it lessening or is it staying constant?

MR. HASTINGS: He has made a study, has he?

THE COURT: If there has been an increase.

THE WITNESS: These are studies from published figures.

MR. HASTINGS: Now we are going into other things.

THE COURT: Never mind the other things.

THE WITNESS: I have made a study of the figures published by the Federal Government.

MR. HASTINGS: We wanted to get in the Dorn study, the Hammond-Horn study, and we have not been permitted to get them in.

MR. BRADFORD: I am asking about the Federal statistics.

THE COURT: They will be the best evidence and not the doctor's statement.

MR. BRADFORD: Your Honor, the Government does not analyze them. They publish the figures and this man studies them and analyzes them.



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THE COURT: I say the figures themselves are the best evidence. If you have them and you want the doctor to explain them, I would be happy to let you do that.

MR. TOOTHMAN: We have the books here.

MR. HASTINGS: I would like to look at them. I probably will have no objection to them. We would have no objection to show the trend.

THE COURT: Let the whole book in, as far as that goes.

MR. HASTINGS: Not just one year.

THE WITNESS: I would report on the trend. The trend has been increasing, but the rate of increase is definitely declining, that is, it is not increasing as fast as it was before.

THE COURT: This whole case is full of that--it has been on the increase. Some say increase rapidly and this doctor says it is not so rapidly. The rate is declining.

Is that right?

THE WITNESS: The rate of increase is declining, yes, sir.

BY MR. BRADFORD:

Q Doctor, draw us a line on the board to illustrate what you mean by that, if you could do so.

A As I said, we have no information on cancer of



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the lung prior to 1939; so we are not going to be able to go back earlier than, say, 1940. Let us say we are dealing with up to 1960.

This is the year and this, let us say, is the mortality rate due to cancer of the lung (indicating). This would be per hundred thousand persons in one year.

If we are talking about, let's say, primary cancer, we would have one graph; if we had all cancers, obviously we would have another.

I will sketch in roughly the primary ones. If this is about five, ten, fifteen, twenty, I'm not sure exactly where it was here because we do not have much of this information, but roughly it has been like that (indicating).

It is still increasing, but it is leveling off, so to speak.

What is likely to happen there, of course, it would be anybody's guess, but as of now it is around twenty or twenty-two deaths per hundred thousand of primary lung cancer.

Q Twenty-two deaths per hundred thousand of primary lung cancer. Does that take into account the kind of lung cancer, whether it is adeno or---

A No, sir, this information is not available.

Q Sir, let us assume that cigarette smoking has



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increased over the last twenty years.

Has there been an increase in cancer, primary lung cancer cases, that correlates or is comparable to the cancer figure you have just drawn up there? In other words, has the lung cancer increased in proportion to or along with the increase in cigarette consumption?

A I have not studied exactly the trend in smoking of cigarettes.

MR. HASTINGS: We will move, then, to strike any answer.

THE COURT: If he does not know the increase in cigarettes, he could not assume anything.

MR. BRADFORD: I think we have some statistics about the increase in cigarettes. I am asking him to assume it.

MR. HASTINGS: He said he has not made a study.

THE COURT: I think we can all answer that question as well as he can if we assume something.

THE WITNESS: The only information on cigarette smoking was done by the census at one time.

BY MR. BRADFORD:

Q I believe that you were a member of the standing committee on the National Office of Vital Statistics, were you not?



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A Yes. I have been for the past, roughly, eight to ten years.

Q Are you still on that?

A No. My term expired July 1, 1964.

Q What were your duties, roughly, in that position?

A To advise the Federal Agency, which is now called the National Vital Statistics Division, on problems associated with the collection of vital statistics.

Q Doctor, would you tell us what a risk is? When you are talking about a risk or prediction or likelihood, tell us what you mean.

A In terms of disease?

Q Yes, sir.

A It is the probability that a person will develop a disease or death within a specified period of time.

You have to pin it down to a period of time. For example, if it is one in a hundred, it means within a year that one person will die within a year if you had a hundred average persons to begin with.

Q Can an estimate as to risk be made unless there is a random selection and representative group such as you put on the board awhile ago in your diagram?

A No. As I just said, the hundred would have to



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be a random group or representative group.

Q Would just the association of figures be any proof of anything scientifically as to cause and effect?

A Not as far as cause and effect is concerned.

Q Doctor, if a doctor reviews a number of lung cancer cases that he has seen in a clinic over a period of years and determines the number of smokers and non-smokers, in your opinion could any valid prediction or conclusion of the risk of the non-smokers to get lung cancer be made on the basis of such a review?

MR. HASTINGS: I think it is a medical question. I object.

THE COURT: Sustained. He has already stated in his opinion unless you have a controlled group, which would manifestly be impossible in cigarette smoking, in his opinion, the statistics on cause and effect relation would be inaccurate and not dependable.

Is that what you said?

THE WITNESS: Yes, sir.

BY MR. BRADFORD:

Q If you take the best scientific method that you have outlinedup there, that is, the best known to science as to statistical studies and you come to the conclusion as to the number from a statistical association, is further



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scientific research necessary to go back to relate the cause and effect?

A Yes.

Q Tell us what that is, please.

A As his Honor has just said, it is--

MR. HASTINGS: I think it is repetitious. We went through this in the beginning.

THE COURT: He has already answered it. Let him explain it. He may have something new. I don't know what the doctor will say.

MR. HASTINGS: He said further evidence of statistics alone does not prove anything.

THE COURT: He said it would not be sufficient to reach an ultimate conclusion that would be dependable.

Is that what you have stated?

THE WITNESS: Yes.

THE COURT: And why would they not be?

THE WITNESS: For the simple reason they are purely association and not cause and effect.

BY MR. BRADFORD:

Q Doctor, if you assume just for the purpose of this question that men who give up cigarette smoking for more than a year prior to the entry in a study such as we have been talking about here had a lower lung cancer rate than those



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who continued to smoke the same amount, would that prove anything with respect to smoking as a cause of lung cancer in the general population, sir?

A No, because you would have to know a lot more information as to why they stop smoking.

Q Doctor, based upon the Bureau of Vital Statistics report that you have studied, do one in ten smokers get lung cancer?

A No.

Q Sir, is it possible to predict the risk of a smoker dying of lung cancer in the lifetime from a statistical point of view?

A No. Of a smoker?

Q Yes.

A No, for the simple reason we do not know what the projected mortality will be of persons who are smokers. We don't know what the future incidence of lung cancer will be for persons who are smokers.



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Q. Is there any valid basis for the estimate that 84 per cent of the lung cancer, or 80 per cent of lung cancer death per year, or any percentage of lung cancer per year is caused by sigarette smoking from the angle of your statistical study?

MR. HASTINGS: Just a minute. The doctor has not done any original statistical study, as I understand it. I object to the question because he is not a medical doctor, and furthermore--

THE COURT: I will sustain the objection.

BY MR. BRADFORD:

Q. Doctor, will you explain why one in ten of cigarette smokers do not get lung cancer based upon your studies of the Bureau of Vital Statistics figures?

MR. HASTINGS. Again I object, your Honor.

THE COURT: I will sustain the objection.

He can explain his criticism of the statistics, if he likes.

MR. HASTINGS: Of the Bureau of Vital Statistics.

THE COURT: Yes. And he can point out where they belong, in his own opinion. He can't say why one in ten doesn't get lung cancer for obvious reasons,



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and I don't think anybody knows why they do and why they don't.

THE WITNESS: I think one in ten would be preposterous in terms of what we have observed.

MR. HASTINGS: Your Honor, I think he would be a competent witness on what he observes; but I don't think that is proper, because he is not a medical doctor.

THE COURT: I agree with you and I will strike the answer.

Strike the question and let's go back.

MR. TOOTHMAN: Can we change it to "whether," which is a statistical problem?

THE COURT: No. He can only criticize the statistical make-up. That is his only qualification. He cannot criticize the basis or the methods employed except the make-up; and I think that is what he is trying to do as near as I can gather.

BY MR. BRADFORD:

Q. Doctor, if you assume that there are a little over 62 million smokers of cigarettes regular in the United States, based upon the Bureau of Vital Statistics of the United States and 10 per cent of them, or one out of ten, get lung cancer, how many lung cancer cases would you have?



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MR. HASTINGS: Over what period? Over a period of 30 or 40 years or what?

I don't think that is a proper question, your Honor. He's talking about statistics appearing in one year. In other words, 40,000 out of 62,000,000, or whatever number there are.

I think the proper question is over a period of 20 or 30 or 50 years.

BY MR. BRADFORD:

Q. The figure of 40,000 that you mentioned was not based on primary lung cancer--

MR. HASTINGS: On the contrary, I think it is based on primary.

THE COURT: Tell us what criticism you have of the statistics of the Bureau, if you have any criticism. Why, in your opinion, they are badly presented or wrongly contrived or whatever criticism you may have?

THE WITNESS: If the lung cancers themselves constitute right now, of course, only about 2 per cent of all deaths, and if this were the figure as you quoted, obviously we would have more lung cancer than we now have. Persons have been smoking for many years.

For instance, in 1955, when the Bureau of Censors, did this survey of smoking habits, there were



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almost 9 million people who were smoking for 25 years or more. If they had been smoking for 25 years or more, they obviously were in the lung cancer figure. And if there were still 9 million of them around who were smoking that length of time within the last ten years, certainly many of them would have died if this ten-figure meant anything. We still only get 18,000 or 20,000 primary lung cancers. And these 9 million males over the age of eighteen--

MR. HASTINGS: We are going to move to strike that.

The evidence that he is speaking is one out of ten in heavy smokers. We are not talking about people that smoke one cigarette or two cigarettes, which the doctor is talking about. He is talking about smokers in general. The statistics were given him on heavy smoking.

MR. TOOTHMAN: That has been Mr. Hastings' version of what the evidence is.

THE COURT: I think Mr. Hastings is correct. If you are going to give him a question, give him one based on something that is already in evidence.

Say that Witness So-and-So said So-and-So.

BY MR. BRADFORD:

Q. Doctor, in the 2 per cent that you talked



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about, that is cancer of all types and all parts of the body, isn't it?

A. Yes.

Q. Not just lung cancer?

A. No, no.

Q. 2 per cent of all deaths?

A. 2 per cent.

Q. Of all deaths?

A. Are lung cancer.

Q. Of all types?

A. Of all types.

Q. As related to the total number of deaths, Doctor, according to the Bureau of Vital Statistics, what would be the chances of a smoker dying of lung cancer on the basis of the figures that we have been talking about?

MR. HASTINGS: Just a minute. He has done no original study, and Vital Statistics has not given any figures that have ever been in evidence.

THE COURT: Sustained.

MR. BRADFORD: Your Honor, could we have a few minutes break at this time? I have left some records at the office, and these figures that Mr. Hastings was asking about, about 1955, I thought I had them here.



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THE COURT: Will it take about five minutes?

MR. HASTINGS: I can start my cross-examination and stop when he comes back.

THE COURT: All right, go ahead meanwhile.

CROSS EXAMINATION

BY MR. HASTINGS:

Q. Dr. Greenberg, in North Carolina, are you under or is your department or your college under any tobacco grants?

A. No.

Q. Have you received any?

A. No.

Q. Are you compensated or do you expect to be compensated for your work here and your preparation, et cetera?

A. I expect to be, yes.

Q. Doctor, these statistics that you put up here, you are talking about primary here?

A. Yes.

Q. Doctor, with respect to primary and unspecified, what would the curve be?

A. The curve would be exactly the same, only roughly double. As you know, the figures that we are



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getting, when the figures are broken down, as to whether they are primary or unspecified, roughly they are about the same. So that the figure would be or the scale would be 10, 20, 30, 40, but the shape of the curve would be the same.

Q. You made the statement that the classification of primary and other classifications of cancer of the lung is unknown. That is not correct, is it?

A. No, I didn't say that.

Q. I think you did, Doctor.

A. Unknown as to whether it is primary or secondary.

Q. Really it is not unknown. It is actually unspecified; isn't that the term that the Bureau of Vital Statistics used?

A. Yes.

Q. And when it states "unspecified," many doctors when they are writing their diagnoses, write their diagnoses on the death certificate and will write down what it is and they will write CA of the lung, and do not specify whether it is primary or what; is that correct?

A. Yes.

Q. So that when we see that on a death certificate, CA of the lung, since it does not say anything, whether it is



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primary, you put in or you place that in the so-called unspecified category; is that right? Is that your understanding of it?

A. If that is the only piece of information on the death certificate, yes. It would be classified in the Ruprecht 163, which is called unspecified as to whether primary or secondary. There is sometimes supplemental information provided on the death certificate where the physician may say there was metastasis, in which case it would be definitely secondary.

Q. If a cancer originates in the liver and goes up to the lung; in other words, if it is primary in the liver and goes up to the lung, it is called cancer of the liver, isn't it, with metastasis or secondary to the lung, isn't it?

A. Yes.

Q. So that among them there would be an overwhelming majority of cancers of the lung, when they are unspecified as primary in the lung?

A. I think I just said that. Some of them can come from other parts of the body and metastasize to the lung.

Q. Yes. But if they are primary in the liver, will it not say cancer of the liver with metastasis to the lung?

MR. BRADFORD: Just one minute. Counsel stopped me from asking that same question dealing with medical



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knowledge and medical background. He just held me to the statistics.

MR. HASTINGS: I will withdraw it.

THE COURT: He admits defeat on that.

BY MR. HASTINGS:

Q. In other words, we can agree, Doctor, that if it is unspecified, it may well include primary.

A. Oh, yes.

Q. What you are talking about is just those that are definitely stated to be primary?

A. Yes.

Q. In this figure, you were giving per cent per year. That means each year rather than--

A. That is the per year death rate. It is 2.4 or 2.6 per hundred thousand.

Q. Doctor, whatever information you have with reference to your knowledge, shall we say, of this subject, you submitted it, did you not, to the Surgeon General's Committee on smoking and health?

MR. BRADFORD: Just one minute.

MR. HASTINGS: I am not asking what he submitted. I am asking did he submit.

BY MR. HASTINGS:

Q. Did you submit any material to the Surgeon



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General's Committee on smoking and health?

A. Yes.

Q. Bernard G. Greenberg, Ph.D. Is that your name?

A. Yes. I was a consultant to the Surgeon General Committee.

Q. You gave them the benefit of whatever knowledge, no matter what knowledge it was, that you had?

A. When I was asked.

Q. Can you tell us, Doctor, if, in your opinion, on this committee there were competent and reputable statisticians?

MR. HASTINGS: I am not asking what they are. I am just asking whether they were on the Surgeon General's committee.

MR. BRADFORD: Just a minute. Even if he knew, it wouldn't be proper for him to state. I think it encompasses too much and goes to something--

THE COURT: I think so. Reframe your question.

BY MR. HASTINGS:

Q. Were there statisticians on the Surgeon General's Committee?

MR. BRADFORD: Just one minute, your Honor. That matter has been taken care of by the Court.

THE COURT: What difference does it make?



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MR. BRADFORD: I object to it as being immaterial.

MR. HASTINGS: I think he has gone quite far afield in the field of statistics and I think I have a right to determine the doctor's qualifications.

THE COURT: Well, I will let him answer it if he can.

THE WITNESS: Yes, there was one statistician on that committee.

BY MR. HASTINGS:

Q. Was there an epidemiologist, also?

A. Yes.

MR. HASTINGS: May I ask the reputation of this statistician?

THE COURT: No. That is his conclusion and is out of the expert line.

Q. (By Mr. Hastings) You have never done personally any original statistical work on the relationship of tobacco and/or smoking and cancer; is that correct?

A. Yes, I have.

Q. You have done some original work?

A. Yes.

Q. Where was that published?

A. In the annals of surgery.



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Q. Could you give us the reference on that?

A. It is in your Surgeon General's Report that you have there. It's one of those listed. It's primary author is Dr. Peacock.

Q. Then it was Dr. Peacock's works, I take it, that you were working on?

A. I was collaborator with him, yes.

Q. Did you do any personal original work on any statistical study, yourself?

A. Well, part of my work was on this study.

Q. We are not permitted to go into the work of other people.

A. It's my work, too. I am a co-author.

Q. So the report is with you as co-author. We are not permitted to go into what others have done. The Court has stated we are only permitted to go into what original work was done by you. You have not done, personally, any work in terms of any correlation or in terms of pathological relationship between slides and smokers?

A. I'm not a pathologist.

Q. You mentioned that the prospective studies did not show or did not use random samples. Let me ask you if it is not a fact that the Doll-Hill Study, which was a prospective study--



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MR. BRADFORD: Just one minute.

MR. HASTINGS: None of them used random samples. I think I have a right to ask this question, your Honor.

MR. BRADFORD: He's going into the report of someone that I cannot cross-examine on.

THE COURT: Not the details. Just ask him.

BY MR. HASTINGS:

Q. The Doll-Hill Study was obtained in a controlled group by ascertaining the smoking habits of the general population in a random sample of the area in which their hospital was located; is that correct, to the best of your knowledge?

A. The Doll-Hill was a physicians study, not a random sample of the lung cancer of people.

Q. I am talking about control. Do you know the difference between controls and actual treatment?

A. Yes.

Q. We are talking about control. I am asking you whether they did not ascertain the smoking habits of the general population by using the area in which their hospital was located, the people in that area. Is that true or not?

A. Yes.

Q. Doctor, can you tell us, by way of your qualifications, how many retrospective studies that you have spoken of showed an association between smoking and lung cancer?



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MR. BRADFORD: Just one minute. Counsel is going into something that I did not go into.

THE COURT: You didn't say he did. You assumed that he did. Ask him whether he looked at any and then start from there.

BY MR. HASTINGS:

Q. Doctor, have you looked at any retrospective studies?

A. Yes.

Q. Can you tell us how many retrospective studies there were that showed an association between tobacco and lung cancer?

THE COURT: Wait a minute. That you have looked at. How many have you looked at?

THE WITNESS: This is very difficult to answer.

BY MR. HASTINGS:

Q. What is your best estimate of those that showed an association?

A. In detail perhaps--

MR. BRADFORD: Wait a minute. The association has to come out.

MR. HASTINGS: I'm not asking for causal relationship. I'm asking for association. That is all the



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doctor said.

MR. TOOTHMAN: He is trying to get the same thing in with the use of different words.

THE COURT: How many have you looked at?

THE WITNESS: In detail, perhaps about ten.

BY MR. HASTINGS:

Q. And how many prospective studies have you looked at, shall we say, in detail, that showed an association between smoking and lung cancer?

MR. BRADFORD: Association with what?

THE COURT: On the question of causation of lung cancer and involving also tobacco smoke.

THE WITNESS: As far as this association is concerned in terms of prospective studies, there are four.

BY MR. HASTINGS:

Q. Did you look at those?

A. Yes.

MR. HASTINGS: I will not ask him to go into them.

BY MR. HASTINGS:

Q. Will you name them so we will know what we are speaking about?

MR. BRADFORD: I object to that, your Honor.

THE COURT: Ask the question and I'll know what to rule on.



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BY MR. HASTINGS:

Q. Sir, can you give us the names of the prospective studies that you have spoken of, without telling us any more than just what they were?

MR. BRADFORD: I object to that because we have not gone outside of the record into the studies of other people.

THE COURT: Overruled.

THE WITNESS: These were varying periods of time. I don't know the details, but during the past ten years or so, the first one was the Hammond and Horn American Cancer Society Study.

Then the Doll-Hill Study of the British physicians.

And there is the VA Study by Dr. Dorn.

BY MR. HASTINGS:

Q. The VA Study. Do you mean the Veterans Administration Study?

A. Veterans Administration Study, Dr. Dorn.

And then the second, the American Cancer Society of Cuyler Hammond.

Q. Did the number of people that were studied run into the hundreds of thousands?

MR. BRADFORD: Just one minute. Again we



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are going into the contents.

BY MR. HASTINGS:

Q. This was not a small group, was it, or was it important to get a large group?

A. They had a large number.

Q. Hundreds of thousands, Doctor?

A. I believe it was a large number. I don't recall the exact number.

THE COURT: He said those studies were no good.

MR. HASTINGS: I don't believe he said they were no good.

THE COURT: He said all studies so far were not good, in his opinion.

MR. HASTINGS: May I correct that a minute? I don't think he made that statement because that actually wasn't asked or permitted. I think he said there were many defects in the prospective studies.

THE COURT: That's the same thing. If a car has many defects, it's no good as an automobile.



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Q Doctor, would it be fair to say that in the ralm of medical knowledge it is very difficult to get a perfect statistical study of anything?

MR. BRADFORD: He is asking within the realm of medical knowledge.

BY MR. HASTINGS:

Q Within your field.

A Is it possible to get the kind of design I did?

Q No.

THE COURT: What he means, all studies of this type---

BY MR. HASTINGS:

Q Within your field.

A Is it possible to get the kind of design I did?

Q No.

THE COURT: What he means, all studies oi this type---

BY MR. HASTINGS:

Q Isn't it rather uncommon to find or be able to get studies which have all the variables, shall we say, which should be theoretically and ideally in place?

A We strive to get as ideal or as perfect a



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study as we possibly can.

Q I am talking about striving. I am talking about the fact that is it not true that it is uncommon to be able to get this because of inherent errors, whatever they may be?

A I wouldn't say it was uncommon. Certainly, in clinical trials it is quite the reverse. It is quite common.

Q In perspective studies is it fairly common or uncommon?

A These are clinical studies I am talking about.

Q Is it not a fact that we determined that the drug Thalidomide that caused the children to have loss of their arms and so on, wasn't the whole causation arrived at purely and solely on statistical studies, and isn't it also a fact the polio vaccine that was found to be containing the actual polio and caused polio in people, that that was arrived at---

A Repeat that again. The polio vaccine?

THE COURT: One question at a time How about that drug?

THE WITNESS: The Thalidomide?

BY MR. HASTINGS:

Q Yes.

A Yes.

Q Type 3 oral poliomyelitis vaccine, is it not



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true that the statistical evidence, the conclusions, were based upon the human statistical observance of what happened? You know what I am talking about.

A The live virus vaccine?

Q Yes. Wasn't that arrived at on a statistical basis?

A I don't know what you mean by a statistical basis.

Do you mean a retrospective basis?

Q It would have to be.

A The word statistical basis is being used very loosely.

Q It would have to be retrospective, would it not?

A Yes. The other polio studies I thought you had reference to was on the Salk vaccine that was well controlled.

Q I am talking about the one that caused the disaster.

A Yes, on a retrospective basis.

Q Then there hasn't been much argument that actually even though it was a retrospective study, there hasn't been much argument that the Thalidomide was the cause of the children's loss of extremities?



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A This is accepted today.

Q And there hasn't been much argument that Type 3 polio vaccine that had the live virus in it was the cause of the---

A Dr. Sabin disagrees with that.

THE COURT: He asked you whether you disagree?

BY MR. HASTINGS:

Q As far as you know, Doctor.

A I have no opinion on this.

Q But you do accept the Thalidomide?

A Yes.

Q Doctor, under this article that you are speaking of that you and Dr.--rather Dr. Peacock, I gather, was the one you collaborated with, that did not have anything to do with cigarettes and the development of lung cancer, did it?

A No.

Q I misunderstood you.

So, you have not made any original study with Dr. Peacock or without Dr. Peacock in regard to cigarettes and lung cancer?

A No.

Q Doctor, if we found an increase in a substance which you believe, not believed but are actually just trying to determine is or is not related to the development of a



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disorder or disease and you find this particular substance, whether it be cigarettes or whatever it may be, that as they increase the incidence of the disease increases, and then you further found that as you cut down the amount of smoking, or whatever it may be, that the incidence likewise of deaths decreases, would it not be further or at least better, shall we say, evidence of the fact that there--- In other words, there is stronger evidence than if you had alone the mere correlation that when one went up the other went up and when one went down the other went down.

Wouldnt that add a little more credence, let's say, to the possible causal relationship, in your opinion?

MR. BRADFORD: I object to that because I tried to draw the similarity between the increase in smoking of cigarettes and counsel objected.

MR. HASTINGS: He drew it and, as a matter of fact, he asked the question and the doctor answered it.

Did you not, Doctor?

THE WITNESS: I can't remember.

THE COURT: I think he did answer the question.

What he simply stated is---

THE WITNESS: Shall I answer the question?

THE COURT: Respecting the view of the situation, if it adds up on two counts---



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THE WITNESS: The answer is no. You have a spurious association, and even if you have a perfect association if it is still spurious it is still spurious regardless of the magnitude. The answer is no.

BY MR. HASTINGS:

Q If you had only the one correlation that when one went up the other went up, would it not be more proof if one went down and the other would go down?

A The answer would be no. You have increased the magnitude of the correlation and it may simply be a spurious association.

Q Would it not be to your mind more suspect not only if one went up that the other went up, increased smoking, increase the lung cancer, but when you decrease the smoking you likewise decreased the incidence of lung cancer?

A No, because the common factor that may be related to these is the same thing which is changing.

I was not allowed to discuss this common factor before.

Q Doctor, are statistics useful in establishing causation of a disease if they are combined with other experimental or observational data?

A What kind of statistics?

Q Statistics such as you teach or that you have



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studied or that you have a background in?

A Yes, obviously.

You want to reproduce them in animals and you want to reproduce them in other groups. Experimental evidence of this kind.

Q And observational studies?

A Observational studies of the kind you are talking about are the kind which epidemiologists do and are extremely valuable in suggesting clues. They have no relationship to proving causation.

Q Isn't statistical evidence helpful in determining causal relationship when it is combined with other evidence, other scientific evidence, or is it of no value at all?

A You mean retrospective studies?

Q Any kind of study. Thalidomide we have agreed is retrospective.

A It is helpful in the sense that it suggests clues.

Q Doctor, one of your observations was that troubles with one of the studies, if you have somebody select, particular people select you, and you and you and you, is it not true that some of these prospective studies, and I am referring to the Dorn study, they didn't really select it, they just took all veterans that held insurance policies?



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MR. BRADFORD: Just a minute. Counsel is trying to get into studies---

THE COURT: Sustained.

MR.HASTINGS: I am merely asking if it was true or not true that---

THE COURT: That is going into it.

MR. HASTINGS: That is all.

THE COURT: We will take a ten-minute recess.

(Thereupon, a short recess was taken after which the following proceedings were had:)

THE COURT: Bring the jury in.

(Thereupon, the jury returned to the courtroom after which the following proceedings were had:)

THE COURT: Have you finished your cross examination?

MR. HASTINGS: I have one question.

THE COURT: All right, if you have another question.

BY MR. HASTINGS:

Q I was asking you, sir, in terms of association leading to a conclusion of cause that if a factor, let's say of smoking, that if you smoked that there was a correlation



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betwemn the incidence of lung cancer, and that was one factor, and whether another factor was if you stopped smoking that there was a decreased incidence. The question I want to ask you now is would it not be even further significant to you as a statistician that the amount of smoking and the incidence ofcancer--in other words, if you smoked a half a pack a day, that there would be this much in terms of development of lung cancer, and a pack a day there would be more and two packs a day there would be even greater incidence and further that there would be greater incidence.

Would that not be of significance to you as a statistician that all of those factors taken together, more than the factor of simply smoking and developing lung cancer---

A It is alwe: interesting to look at these. It still doesn't prove the ca=e.

For example, if a person is smoking because he is of a psychological disposition to smoke, the more he smokes the more he is in that particular psychological disposition and, therefore, he may get a greater risk of developing lung cancer.

Again, this common factor, which may be related to both, mainly smoking and lung cancer, is tied in with this degree of association you are talking about. So, you have not



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helped the case. You have at least thrown away the possibility of discounting it, but you really haven't made that much progress toward proving causation.

Q Sir, are you familiar with the study done on the seventh day adventists?

MR. BRADFORD: Your Honor, counsel is going---

MR. BRADFORD: It is part of the answer the doctor just gave.

THE COURT: He can answer yes or no.

BY MR. HASTINGS:

Q Are you familiar with the study done on the seventh day adventists?

A On cigarette smoking and lung cancer or cigarette smoking and pregnancy? The way your question was worded--- I'm sorry.

THE COURT: Lung cancer.

THE WITNESS: I know of its existence. I do not know the details.

MR. HASTINGS: That is all.

REDIRECT EXAMINATION

BY MR. BRADFORD:

Q Doctor, counsel mentioned the fact of statistical studies in the use of the drug Thalidomide.

Was that confirmed in lab studies, sir?



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A Yes.

Q You mentioned also the study of polio.

Do you know whether or not in the polio tests that were made they used a double blind and also the placebo test to determine the statistical relations, and did they not also have the germ isolated?

A In the 1954 field trials of the Salk vaccine, the first vaccine which was developed, they used a placebo and a true control in following the design I am talking about.

MR. HASTINGS: We are not talking about type 3, are we?

THE WITNESS: No. That is another one. He asked the question in rather general terms.

The latter part, would you repeat that?

BY MR. BRADFORD:

Q And did--- One was related to the placebo and one was related to the double blind.

MR. HASTINGS: Not the Type 3 poliomyelitis vaccine?

MR. BRADFORD: I will get to the Type 3 you talked about.

BY MR. BRADFORD:

Q The Type 3 he was talking about, did they isolate the germ?



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A Yes. In the case of poliomyelitis we know the three types of organisms that cause the disease, and this type of organism was found in the feces of the persons that had the disease, that specific type.

Q So, the specific type of vaccine that was given was found in those people, was it not?

A Right.

Q The fact that a large number of people that had been used, in a study like Mr. Hastings referred to, a large group, if you add to a small group or use a large group of people in a study, does that make the study acceptable if the method is not acceptable?

A As you increase the sample size, you obviously get closer to the target population. Unless you get the entire target population, if you have a bias in the way of selecting your sample, simply having a large sample does not overcome the defect in the method. So, all you do, really, is repeat the area you made the first time and second time.

A large sample of and by itself is not wholly, so to speak. It depends on how the sample was picked, regardless of the size.

MR. ERADFORD: No further questions.

(Witness excused.)

MR. ERADFORD: We will call Dr. Little.



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